PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification [5]: A61M 29/00	A1	(11) International Publication Number: WO 95/23008
		(43) International Publication Date: 31 August 1995 (31.08.95)

(21) International Application Number: PCT/US94/02246

(22) International Filing Date: 28 February 1994 (28.02.94)

(71) Applicant: QUERALS & FINE, INC. [US/US]; 11839 N.W. 28th Street, Coral Springs, FL 44065 (US).

(72) Inventors: QUERALS, Louis, A.; 800 South Sharp Street, Baltimore, MD 21230 (US). FINE, Michael, J.; 11839 N.W. 28th Street, Coral Springs, FL 33065 (US).

(74) Agent: BARRON, Harry, W.; Suite 202, 8221 Glades Road, Boca Raton, FL 33434 (US).

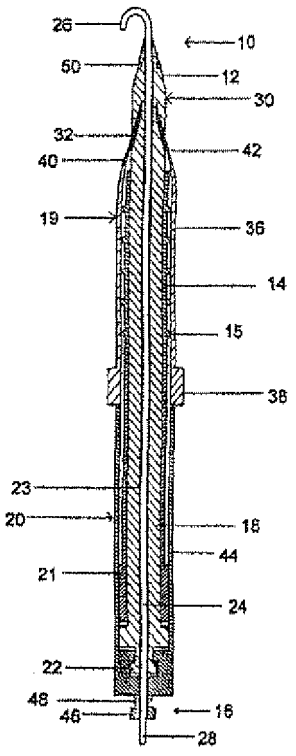
(81) Designated States: AU, BR, JP, KR, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: INSERTION TOOL FOR AN INTRALUMINAL GRAFT PROCEDURE HAVING LOCKING FEATURES

(57) Abstract

A tool (10) for the intraluminal insertion and deployment of a tubular graft (14) within a blood vessel includes a shaft (18), a tubular sheath (19), and a deployment slider (21). The slider (21) and graft (14) are slidingly mounted on the shaft (18) and the tubular sheath (19) is slidingly mounted over the graft (14) and a distal portion of the slider (21). The graft (14) is deployed by inserting the tool (10) into the blood vessel, retracting the sheath (19) towards the proximal end of the shaft (18) and over the slider (21). Then the shaft (18) is withdrawn as the slider (21) is held in place to prevent the withdrawal of the graft (14). The sheath (19) is attached at its distal end to the distal end of the shaft (18).



B1

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	**GB**	United Kingdom	**MR**	Mauritania
AU	Australia	**GE**	Georgia	**MW**	Malawi
BB	Barbados	**GN**	Guinea	**NE**	Niger
BE	Belgium	**GR**	Greece	**NL**	Netherlands
BF	Burkina Faso	**HU**	Hungary	**NO**	Norway
BG	Bulgaria	**IE**	Ireland	**NZ**	New Zealand
BJ	Benin	**IT**	Italy	**PL**	Poland
BR	Brazil	**JP**	Japan	**PT**	Portugal
BY	Belarus	**KE**	Kenya	**RO**	Romania
CA	Canada	**KG**	Kyrgystan	**RU**	Russian Federation
CF	Central African Republic	**KP**	Democratic People's Republic of Korea	**SD**	Sudan
CG	Congo			**SE**	Sweden
CH	Switzerland	**KR**	Republic of Korea	**SI**	Slovenia
CI	Côte d'Ivoire	**KZ**	Kazakhstan	**SK**	Slovakia
CM	Cameroon	**LI**	Liechtenstein	**SN**	Senegal
CN	China	**LK**	Sri Lanka	**TD**	Chad
CS	Czechoslovakia	**LU**	Luxembourg	**TG**	Togo
CZ	Czech Republic	**LV**	Latvia	**TJ**	Tajikistan
DE	Germany	**MC**	Monaco	**TT**	Trinidad and Tobago
DK	Denmark	**MD**	Republic of Moldova	**UA**	Ukraine
ES	Spain	**MG**	Madagascar	**US**	United States of America
FI	Finland	**ML**	Mali	**UZ**	Uzbekistan
FR	France	**MN**	Mongolia	**VN**	Viet Nam
GA	Gabon				

INSERTION TOOL FOR AN INTRALUMINAL GRAFT PROCEDURE HAVING LOCKING FEATURES

This invention relates to a tool for inserting and deploying a medical graft within a body cavity, such as a blood vessel, and more particularly, to a tool for inserting and deploying such graft in a femoral-popliteal artery during an intraluminal graft procedure.

Balloon angioplasty and atherectomy have generally not proven to be viable long term options in the treatment of extensive atherosclerotic lesions in femoral-popliteal arteries. Good results are only obtainable with such methods when the flow limiting lesions are short and discrete. It is thus apparent that patients with extensive occlusive disease in a femoral-popliteal artery are presently best treated by bypass surgery. Conduits for such bypass surgery can be either autogenous, such as saphenous vein, or synthetic, such as tetrafluoroethylene polymer sold under the brand name "Goretex". The choice of the graft type employed depends on the preference of the surgeon and on the integrity of the outflow tract. This technique is an effective long term option, with patency rates in the 80 per cent range for selected cases. This procedure is one of the most common graft procedures, with 25,000 to 30,000 cases being treated each year.

In accordance with the standard procedure for providing such a bypass, a surgical cutdown is performed in the groin area and in the leg, thereby providing cutdowns above and below the diseased portion of the blood vessel to be bypassed. A tunnel is made along side the diseased artery between the cutdown areas, and the graft or prosthesis is passed through the tunnel. After the graft or prosthesis is sutured to the femoral end of the artery at the cutdown in the groin area and to the popliteal end of the artery at the lower cutdown, blood flow is restored through the affected leg. This procedure generally takes 2½ to 3 hours, with a recovery time lasting 5 to 6 days. Disadvan-

tages of this procedure include the requisite spinal or general anesthesia, the requirement for two incisions, the length of surgery, with significant morbidity and mortality, and the length of time required for recovery.

A number of U.S. Patents describe methods for inserting a radially expandable, generally tubular prosthesis, stent or graft in a blood vessel. The prosthesis has a contracted state, in which it is carried to a diseased portion of the blood vessel by means of an insertion tool, and a radially expanded state, which it assumes upon being released by the insertion tool. The insertion tool includes means for holding the prosthesis in its contracted state, whereby narrow and obstructed blood vessels can be traversed. After the deployment, the expansion of the prosthesis forms a central hole suitable for blood flow and, with radial compression forces, seats the prosthesis in place within the blood vessel. After the procedure, the prosthesis continues to be held in place by these compression forces.

For example, U.S. Patent 4,665,918, issued to Garza et al on May 19, 1987, describes an implant tool having an outer sheath covering the prosthesis and holding it in a contracted state during the insertion procedure. The outer sheath is slidably mounted over a delivery catheter and within a tubular outer catheter. At the proximal end of the device, a first pair of locking arms, variable in effective length through attachment at a plurality of notches, is used to determine how far the delivery catheter extends from the outer catheter; and a second pair of locking arms is used to hold the sheath in place over the prosthesis. When the obstructed portion of the blood vessel is reached, this second pair of locking arms is removed, and the outer sheath is pulled outward, uncovering the prosthesis, which expands radially, pushing away obstructive material in the blood vessel and providing a clear central hole, through which the distal tip of the insertion tool is withdrawn.

In another such example, U.S. Patent 4,732,152, issued to Wallstén et al on March 22, 1988, describes an insertion tool having an outer tip portion consisting of a hose folded back within itself, leaving a double-walled cavity in which a prosthesis is held in its contracted state. The hose is connected to a pressurized cylinder, which is slid outward on a central shaft, pulling the fold in the hose outward to expose the prosthesis, which then expands in the blood vessel. Alternative embodiments of the insertion tool include an inflatable balloon ahead, behind, or around the double-walled cavity, provided for widening the blood vessel before the prosthesis is released at a desired location.

U.S. Patent 4,875,480, issued to Imbert on October 24, 1989, describes a means for providing the circulation of a liquid flushing medium to remove gasses, such as air, which might be trapped in the cavity with the prosthesis prior to deployment of the prosthesis. Means are also described for flushing gasses from the folded back part of the hose to eliminate the danger of releasing gasses into the bloodstream in the event of a rupture in the hose.

U.S. Patent 4,771,773, issued to Kropf on September 20, 1989, describes an insertion tool for placing a prosthesis in the form of a helical spring within a blood vessel. In a released, or deployed state the prosthesis has a larger diameter. For insertion the prosthesis is wound, by the rotation of one end, tightly on a mandrel forming a part of the insertion tube, having a diameter smaller than the inner diameter of the prosthesis. Each end of the prosthesis is fastened to one of a pair of axially separated fasteners, which are in turn mutually connected by a transmission in the area of the mandrel. The transmission allows relative rotation of the fasteners only in the direction which tightens the helical prosthesis, until a clutch is actuated to allow rotation in the opposite direction. Alternately, one of the fasteners includes a triggering member which releases the associated end of the he-

lical prosthesis. The clutch or triggering member can be actuated from the end of the insertion tool opposite to the mandrel.

U.S. Patent 5,026,377, issued to Burton et al on June 25, 1991, describes an insertion tool for deploying a self-expanding tubular prosthesis, or stent, which is preferably a braided type, within a body canal, such as a blood vessel. The tool includes an elongated tubular outer sleeve, having disposed therein an elongated core which is movable relative to the sleeve. The core has a grip member, at or near its distal end, which is adapted to releasably hold the prosthesis within the outer sleeve. This grip member, which provides a high-friction contact surface between the prosthesis and the core, may be a sleeve or coating of a material which takes a set, such a polyurethane, attached to the core. The prosthesis is carried through the blood vessel, in a contracted state, being held in an annular space between the grip member and the outer sleeve. When the correct position is found, deployment of the prosthesis is begun by pulling the outer sleeve backward, allowing the distal end of the prosthesis to expand against the walls of the blood vessel. If the position of the prosthesis, which is then checked by fluoroscopy is correct, the outward motion of the outer sleeve is continued to release the entire prosthesis; otherwise the outer sleeve is moved back inward to retract the part of the prosthesis which has been extended, and the prosthesis is repositioned as desired. During these motions, the prosthesis is held in position relative to the core by contact with the grip member.

While the prior art devices described above rely on the release of mechanical energy stored in the prosthesis to provide compressive forces necessary to hold the prosthesis in place, the intraluminal grafting system described in U.S. Patent 4,787,899, issued to Lazarus on November 29, 1988, employs a pressurized expandable membrane, operating inside a generally cylindrical prosthesis within a blood

vessel, to force the points of staples fastened to the outside of the prosthesis outward into the walls of the blood vessel. This device is described for use in the repair of a damaged vessel, such as an aneurysm or a torn vessel. The insertion tool includes a flexible rod and a tube arranged to be slid along the axis of the rod. The distal end of the rod mounts a cup, having an open end facing away from the distal tip, in which a collapsed prosthesis is carried, extending around the distal end of the tube. The prosthesis is preferably made of nylon, dacron, or Teflon, having a number of circumferential bifolds along its length. The expandable membrane forms a part of the distal portion of the tube. To deploy the prosthesis, the expandable membrane is inflated, and the tube is pulled outward, dragging the prosthesis out of the cup and forcing it against the walls of the blood vessel. The expansion of the prosthesis forms a large enough internal hole to allow the subsequent withdrawal of the cup.

The prior art intraluminal grafting systems described above each require a special type of graft material formable into a compressed state, and releasable into an expanded state. Thus, these systems share the disadvantage of not being adaptable for the deployment of the types of material commonly used in graft procedures, such as the ribbed Goretex tetrafluoroethylene polymer typically used in femoral-popliteal artery bypass operations.

Furthermore, except for the system described in U.S. Patent 4,787,899 to Lazarus, the prior art systems require that the mechanical strain energy stored within the graft material in its contracted state must exert enough pressure on the walls of the blood vessel to hold the prosthesis in place. U.S. Patent 4,787,899 to Lazarus, on the other hand, depends on staples to perform this function. Thus, none of these systems is configured to be used with the common, effective, reliable and approved method of suturing graft material into the healthy portion of a blood

vessel. Further, none of the prior art systems can readily utilize commercially available grafts, which have previously been tested and approved by appropriate authorities.

In accordance with one aspect of the invention, there is provided apparatus for the intraluminal insertion and deployment of a medical graft within a blood vessel characterized by shaft means for slidably receiving the medical graft, a sheath mounted over the graft, and means for selectively securing the sheath to the shaft means.

Preferred versions of the subject invention are hereafter described with specific reference being made to the following Figures, in which:

Figure 1 is an axial cross-sectional view of an intraluminal insertion tool built in accordance with this invention, shown operating on a guide wire;

Figure 2 is a partly sectional side elevation of the sheath used as a part of the tool of Figure 1;

Figure 3 is an isometric view of the distal tip portion of the sheath of Figure 2;

Figure 4 is an axial cross-sectional view of a guide funnel provided as an accessory for the assembly of the tool of Figure 1;

Figures 5 through 8 show the manner of assembling the various components of the tool of Figure 1;

Figure 9 is an axial cross-section view of a an alternative version of the intraluminal insertion tool, including a heated tapered distal section;

Figure 10 is an axial cross-sectional view of a second alternative version of the intraluminal insertion tool, including an integral angioplasty balloon;

Figure 11 is an axial cross-sectional view of a second embodiment of the intraluminal insertion tool, including a mechanism for securing the graft and sheath within the assembled tool;

Figure 12 is a plan view of the center locking ring used in the second embodiment for securing the distal end of the graft and sheath;

Figure 13 is a partial cross-sectional view of the manner in which the proximal end of the graft is secured;

Figure 14 is a partial cross-sectional view of the manner in which the proximal end of the sheath is secured;

Figure 15 is a partial cross-sectional view illustrating alternative structure for securing the distal end of the graft and sheath;

Figure 16 is a cross-sectional view illustrating alternative structure for securing the proximal end of the graft;

Figure 17 is a prospective view of the tool when assembled as shown in Figure 16;

Figure 18 is a cross-sectional view of an alternate version of securing the distal end of the graft;

Figure 19 is a plan view of the tool showing an alternate structure for the securing mechanism of the tool shown in Figure 11; and

Figure 20 is a partial cross-sectional view illustrating alternative structure shown in Figure 19 taken across lines 20-20.

An insertion tool 10 used for performing an intraluminal bypass-type medical procedure in a blood vessel, such as the femoral-popliteal artery, with a conventional and commercially available ringed synthetic graft material, is shown in Figures 1 through 8.

Referring first to Figure 1, insertion tool 10 includes a distal end 12, which extends into the human body during the insertion of a synthetic blood vessel graft 14, and a proximal end 16, which remains outside of the human body, and which is used to manipulate the insertion system so that synthetic graft 14 is delivered to the desired location. Graft 14 is preferably made of a synthetic material, such as a tetrafluoroethylene polymer, and is sold under the brand name "Goretex" by W.L. Gore, of Arizona. Graft 14 includes a number of spaced integral rings 15 around its outer surface, for providing stiffness and to

prevent collapse in use, while allowing the flexibility required to traverse the vascular system and to bend with subsequent motion of the patient.

Tool 10 is designed to carry graft 14 into the body on an insertion shaft 18, while graft 14 is covered by a shield, or sheath 19, as tool 10 is advanced within the body. When the proper location for graft 14 is attained, a safety lock tube 20, which holds sheath 19 in place during insertion, is disengaged and removed from insertion shaft 18, and sheath 19 is slid outward from the body, off the proximal end of shaft 18, outwardly exposing graft 14. Insertion shaft 18 is then pulled outward from the body, while a deployment slider 21 is held in place, so that graft 14 is deployed, being left in place within the body.

Insertion shaft 18 extends the length of tool 10, having a male fitting 22 of a type which can be rotationally locked or unlocked from a mating female fitting, such as a luer fitting, at a proximal end, permitting the attachment of standard medical accessories, such as syringes or hemostasis valves. Shaft 18 also includes an axial hole 23 extending its entire length to allow the infusion or aspiration of a fluid and/or to allow the passage therethrough of a guide wire 24, which may be of a conventional type having a "J"-shaped hook at a distal end 26 and a straight proximal end 28. Insertion shaft 18 is fabricated from a somewhat flexible material, such as polycarbonate and may have a diameter of approximately six millimeters, or less, thereby permitting a slight flexure during insertion into an removal from the body. The distal end of insertion shaft 18 has a tapered tip 30, which dilates the treatment area of the body as shaft 18 is advanced into the human body. A circumferential slot 32 extends inward around insertion shaft 18 at an angle pointing toward tapered tip 30. Slot 32 may be axially displaced along the cylindrical portion of shaft 18 by between 2.5 to 12.7 millimeters from the adjacent end of tapered tip 30 and the depth of slot 32 may be from 1.3 to 2.5 millimeters.

The length of insertion shaft 18 depends on the procedure to be accomplished, and particularly on the length of the synthetic graft 14 to be inserted. For intraluminal femoral-popliteal artery procedures, a graft 14 may typically be 300 to 350 mm in length. Insertion shaft 18 must be somewhat longer than twice the length of graft 14 to accommodate the remaining components of tool 10 and to allow tool 10 to be manipulated as intended. The diameter of shaft 18 is selected approximate the inner diameter of graft 14 so that graft 14 closely fits over shaft 18.

Figures 2 and 3 show sheath 19 in more detail. Sheath 19 forms the outer portion of insertion tool 10 during the insertion procedure. As seen in Figure 2, sheath 19 has a thin tubular portion 36 and a relatively rigid collar 38, which, as discussed hereafter, provides a grip for the physician at the proximal end of sheath 19. Four or more Vee shaped cuts 37 are made at the distal end of sheath 38, thereby forming tabs 42 which may thereafter be pressed together to form a tapered end 40, as best seen in Figure 3, when tabs 42 are inserted in slot 32.

When sheath 19 is assembled on insertion shaft 18 in the manner shown in Figure 1, tabs 42 fit within slot 32 of shaft 18. A guide funnel 52, seen in Figure 4, is provided as an accessory to assist in the assembly of tabs 42 into slot 32. Guide funnel 52 has a cylindrical outer surface 54, an axial hole 56, and an internal truncoconical surface 58. After sheath 19 is moved completely past slot 32, guide funnel 52 is placed over tapered tip 30 of shaft 18, to be held in place while sheath 19 is moved toward the distal end of tool 10. This motion causes the inward deflection of tabs 42 upon contacting truncoconical surface 58, so that tabs 42 are simultaneously fed into slot 32. After sheath 19 is slid fully forward, guide funnel 52 is removed from tool 10.

Since sheath 19 covers graft 14 during its advancement into the body on insertion shaft 18, prior to final deployment, sheath 19 must be constructed of a material,

such as a tetrafluoroethylene polymer, which slides easily through the body. Alternately, other materials with low friction surfaces or slippery coatings, such as hydrogel, may be used. When flexible tabs 42 are held within slot 32, the distal end of sheath 19 is maintained in a tapered configuration, which permits further dilation of the treatment area of the body through which the insertion tool 10 is advanced. The internal diameter of sheath 19 must be large enough to allow sheath 19 slide over graft 14 during the assembly of tool 10 and during the deployment of graft 14 within the body. To facilitate the advancement of tool 10 through the body, it is desirable that the distance from the inner to outer surfaces of tubular portion 36 be as thin as possible, consistent with requirements for strength and stiffness which may be placed on sheath 19 during the usage of tool 10.

Referring now to Figures 5 through 8, the manner of assembling tool 10 and graft 14 is shown. First, as seen in Figure 5, deployment slider 21 is inserted on shaft 18 and then graft 14 is inserted on shaft 18 in front of slider 21. The resulting subassembly after slider 21 and graft 14 are assembled is seen as the left portion of Figure 6. As seen, the length of slider 21 and graft 14 substantially equals the length of shaft from fitting 22 to slot 32. Graft 14 is selected to be the appropriate length for the medical procedure to be performed and preferably, the length of deployment slider 21 takes up the remaining available length of shaft 18. Next, as seen in Figure 6, sheath 19 is inserted over graft 14 and the tabs 42 are inserted into slot 32 using guide funnel 52. At this point, the partially assembled tool 10 appears as in the right portion of Figure 7. Lastly, as seen in Figure 7, safety lock tube 20 is slid over deployment slider 21 and against the back end of sheath 19. Then, safety lock tube is rotated 90 degrees and becomes locked with fitting 22 at the proximal end of shaft 18. In this position, safety lock tube main-

tains tabs 42 of sheath 19 fixedly engaged in slot 32. Now, tool 10 is completely assembled as seen in Figure 8, and ready for use.

As assembled in Figure 8, tool 10 is ready for insertion into a body for the purpose of placing graft 14 in the body. For example, graft 14 may be used as a bypass for a blocked artery, such as the femoral-popliteal artery in a patient's leg. The procedure for inserting tool 10 includes first identifying the area to be bypassed. If the bypass area is a blockage in an artery, an incision is made to expose the lumen of the artery on the proximal side of the blockage. Next, the distal or "J" end 26 of a conventional guide wire 24, as seen in Figure 1, is inserted within the exposed artery to a point on the distal side of the blockage, with the proximal end 28 of the guide wire 24 remaining outside of the body. Next, tool 10 is guided into the exposed artery by axial hole 23 being inserted over the proximal end 28 of guide wire 24. Tool 10 is then inserted into the interior of the artery through the incision in the artery until the distal end of graft 14 is beyond the blockage. During insertion, tool 10 is guided through the artery by guide wire 24 in a well known manner. In assembling tool 10, the length of graft 14 is selected to be appropriate for the blockage area to be relieved and the length of slider 21 is preferably selected to take up the remaining length of shaft 18. Sheath 19 is further selected to somewhat longer than graft 14, so that when tool 10 is fully inserted, collar 38 of sheath 19 remains outside of the patient's body.

The process of deploying graft 14 into a body begins with safety lock tube 20 being rotated to the unlocked position and then being slidably removed. Then, collar 38 is grasped and sheath 19 is slid outward over deployment slider 21. During this step, tabs 42 are removed from slot 32 and expand to slide over deployment slider 21 as well. After sheath 19 is removed, graft 14 is exposed within the artery, which collapses against the outer surface thereof.

The presence of rings 15 particularly maintains graft 14 firmly in place so that it is not easily moved as guide wire 24, slider 21 and lastly shaft 18 are removed. However, to assure that graft 14 remains in position, removal may proceed by the physician holding slider 21 against graft 14 while first removing shaft 18. After shaft 18 is removed, rings 15 provide the strength required to prevent graft 14 from collapsing. After tool 10 is completely removed from the body, the proximal end of graft 14 is preferably attached, by suturing, to a healthy portion of the artery, above the diseased section, and blood flow is restored.

One particular advantage obtained from using tool 10 is that a wide variety of commercially available and thoroughly tested and approved forms of graft material may be used, instead of requiring the use of special forms of graft material having a radially contracted state during insertion and a radially expanded state after deployment, as taught in the prior art. Examples of tools and systems requiring such radially expandable or self-expanding grafts are found in U.S. Patents 4,665,918 to Garza, 4,732,152 to Wallstén et al, 4,771,773 to Kropf, 4,787,899 to Lazarus, 4,875,480 to Imbert, and 5,026,377 to Burton et al.

It should be noted that safety lock tube 20 includes a luer type fitting 46 for the attachment to standard medical devices and an axial hole 48 extending through its proximal end and aligned with axial hole 23 when attached. This structure permits the infusion or aspiration of fluid by means of axial hole 23 in insertion shaft 18. During the advancement of tool 10 through a blood vessel, a contrast medium can be infused through axial holes 48 and 23 to allow visualization of tool 10 relative to body structures under fluoroscopy. Placement of the guide wire 24 through axial holes 48 and 23 into the body assists in navigation of tool 10 through the body, thereby increasing the safety of procedures using tool 10 by following well established practices of guide wire navigation. The diame-

ters of axial holes 48 and 23 are large enough to permit the simultaneous extension of a guide wire and fluid motion therethrough.

In one version of insertion tool 10, tapered tip 30 of insertion shaft 18 may include a metal band 50 which becomes visible under fluoroscopy to provide information to the physician regarding the location of tool 10 inside the body. Alternately, tip 30 can be made using a radio-opaque material of many different types.

As noted above, to prepare for the performance of an intraluminal graft procedure a proper length of graft material 14 must be loaded into the tool 10 and the other components have lengths based upon the length of graft and/or the length of shaft 18. It is anticipated that appropriate lengths of graft 14 and deployment slider 21 will be provided in separate, sterile packages, and that a surgeon will typically have several lengths of insertion tools 10 to be used with several corresponding lengths of graft material. Alternately, fully assembled insertion tools 10 may be supplied in sterile packaging with differing lengths of graft 14 pre-loaded therein, ready for the insertion procedure.

As indicated above, one anticipated application of insertion tool 10 is in the treatment of severe occlusive disease in the peripheral arterial system, particularly in the installation of an intraluminal graft in a femoral-popliteal artery. In this procedure, a single incision is made to expose the affected artery and the diseased artery is traversed, employing either a guide wire or an arthrectomy device. In some patients, an angioplasty balloon may first be used to dilate the artery to a diameter of six to seven millimeters. While balloon angioplasty is not generally successful when applied to a lone segment of occluded femoral-popliteal artery as a treatment, it is often a useful initial procedure to open the artery for the subsequent insertion of graft material.

It is anticipated that the medical procedure described herein can be performed under a local anesthetic in one to two hours with a hospitalization of only a few of days. Thus, significant advantages are gained over the conventional procedure, which requires cutdowns to the artery in both the femoral and popliteal locations, the formation of a tunnel space, adjacent to the diseased artery for the deployment of a bypass graft, and suturing of the graft to the artery at both ends. Such conventional procedures, of course, must be done under a general anesthetic and require significantly longer surgical and recovery times.

Referring now to Figure 9, an insertion tool 60 is shown having an insertion shaft 62 extended and otherwise modified to provide a tapered tip 64 with a circumferential heating element 66, which may be used to soften the treatment site and to assist in the dilation effect needed to advance tool 60 through the body. The temperature range used at this heating element may be from 40 degrees C to 200 degrees C. Heating element 66 may include an inner layer of electrically resistant material, thereby permitting heating by direct current, covered by metal or of some other material capable of sustaining and transmitting the required heat. In tool 60, insertion shaft 62 is formed of a thermoplastic material molded around electrical wires 70 or around wire lumens extending from electrical connectors 72 to heating element 66. A narrow slot 74, extending longitudinally along the tubular portion of safety lock tube 76, allows the assembly and operation of tube 76 as previously described relative to safety lock tube 20 of insertion tool 10, with wires 70 extending outward to connectors 72 through slot 74. Alternately, heating element 66 may be activated by radio frequency energy as can be appreciated by those skilled in the art.

Electrical connectors 72 provide an interface at which wires 70 are connected to a controllable source of electrical current. A number of well known methods for

providing and controlling electrical current can be used to control the temperature of heating element 66. For example, a thermistor (not shown) can be located adjacent to heating element 66 to provide an indication of the temperature, with feedback from the thermistor being used to regulate the electrical current provided to element 66.

Referring now to Figure 10, a cross-sectional view of a second alternative insertion tool 76 is shown. Tool 76 has been modified relative to tool 10 to support an inflatable membrane forming an angioplasty balloon 78 extending from tapered tip 80 of insertion shaft 82. An extended distal cylindrical shaft section 84, having a diameter less than that of main shaft section 86, and a length of 10 to 300 millimeters, is provided for the attachment of balloon 78. A small hole 88, extending along the length of shaft 82, is used to provide a fluid, such as saline solution, water, or contrast media, to inflate balloon 78 at a pressure from one to twenty atmospheres. If insertion shaft 82 is made using a thermoplastic molding process, hole 88 may be provided by including a small diameter multi-lumen extension in the mold as a insert.

Balloon 78 may have an outer diameter of four to thirty millimeters and a length of ten to 200 millimeters and it may be fabricated from irradiated polyethylene, polyvinyl chloride, or other suitable balloon materials well known to those skilled in the angioplasty art. A distal tip 90 of distal shaft section 86 is also tapered, having a profile similar to that of conventional angioplasty catheters. Hole 88 is connected to a tube 90 extending outward to a small luer type fitting 92, which provides a capability for connection to standard medical accessories (not shown). A slot 94 extends along the tubular portion of safety lock tube 96, providing for the installation and removal of tube 96 around outward extending tube 90.

In its anticipated usage, tool 76 provides an additional advantage in simplifying operative procedure by combining the angioplasty procedure required to open the

clogged artery, so that the tool can be advanced therethrough, with the advancement of the tool. When compared to the prior art embodiments including angioplasty balloons described in U.S. Patents 4,732,152 to Wallstén et al and 4,875,380 to Imbert, insertion tool 76 has the advantage of not requiring the use of a radially self-expanding graft. In insertion tool 76, full advantage is taken of the expandable property of angioplasty balloon 78. In its inflated condition, this balloon 76 is capable of opening a blood vessel to a diameter through which tool 76 can pass with the application of a reasonable level of axial force. In its deflated condition, balloon 76 is small enough to pass through the central hole in graft 14. Thus, standard graft materials, not having a self-expanding characteristic, can be used for graft 14, and the complexity included in the Wallstén et al design, required to deploy a self-expanding graft pushing outward on its covering, is not required.

Referring now to Figure 11-19, a second embodiment of an intraluminal insertion tool 100 is shown and hereafter described. Tool 100 differs from the tool 10, shown in Figures 1-10, by including a mechanism 102 for securing a graft 106 and a sheath 104 within the assembled tool 100. Graft 106 and sheath 104 may be similar to graft 14 and sheath 19 shown in Figures 1-10.

One of the problems with tool 10 is that sheath 19 can become loosened during the insertion of tool 10 in the artery. Another problem with tool 10 is that as sheath 19 is placed over graft 14 during assembly of tool 10, graft 14 can move and cover slot 32; further, during deployment of graft 14, when sheath 19 is removed, it can cause graft 14 to be dragged outward and either be mis-positioned in the artery, or even buckle against slider 21. Tool 100 is designed to overcome these problems.

Referring specifically to Figure 11, a cross-sectional view of the cylindrical tool 100 is shown. Tool 100 includes a central shaft 108 having a tapered tip 109

at the distal end 110 thereof, similar to the distal end 12 of shaft 18 shown in Figure 1. The proximal end 112 of shaft 108 includes an upstanding member 114 secured thereto and member 114 includes a proximal facing extension 116 spaced from the main portion of shaft 108 and having inward facing threads 118.

Placed around shaft 108 is a stationary shaft 120, the distal end of which forms the proximal side of slot 122, which generally corresponds to slot 32 in Figure 1 in that it is intended to receive the slotted end of sheath 104. The proximal end of stationary shaft 120 included an inverted "T" shaped extension 124 having outward facing threads 126 and 128 on both arms of the "T". Threads 126 on the proximal side of the inverted "T" are positioned to mate with threads 118 on extension 116. Thus, when the top of inverted "T" is held and extension 116 is rotated, central shaft 108 moves laterally relative to stationery shaft 120. This movement will secure the proximal end of sheath 104 in slot 122, as seen in Figure 14.

A graft securing shaft 130 is placed over stationery shaft 120 and has a distal end with threads 132 mating with threads 128 of stationery shaft 120. An elastic member 134 is placed between the distal end of securing shaft 130 and a lip 136 near the distal end of stationery shaft 120. Elastic member 134 is selected to expand radially when a longitudinal force is applied thereagainst. Such a force is applied when graft securing shaft is rotated while holding stationery shaft 120 as a result of the mated threads 128 and 132. Rotation may occur by holding stationary the leg of the "T" shaped proximal end of stationary shaft 120 while rotating the upward extending proximal end of securing shaft 130.

Thus, the combination of central shaft 108, stationary shaft 120 and securing shaft 130 correspond to shaft 18 in Figure 1. Graft 106 and sheath 104 are placed over the distal half of graft securing shaft 130 in the manner previously described with respect to Figures 1-10.

When assembled, graft 106 extends over elastic member 134; thus, when elastic member 134 expands due to the forward movement of graft securing shaft 130, the distal end of graft 106 is held firmly against sheath 104, as seen in Figure 13.

At approximately the center of graft securing shaft 130, a vertical cutout 138 is positioned to receive a "U" shaped locking member 140 (shown in plan view in Figure 12). Locking member 140, when installed, prevents rearward movement of graft 106 and sheath 104. As seen in Figure 12, locking member 140 includes a pair holes 142 for receiving a filament to prevent locking member 140 from being inadvertently removed from tool 100. On the proximal side of locking member 140 is placed a deployment slider 144, which is similar to deployment slider 21, previously described, except that the thickened portion, held by the physician during withdrawal of the tool 100, is on the distal side thereof.

Referring to Figure 15, an adjustable version for locking member 140 is shown. Specifically, locking apparatus 146 includes a pair of rings, 148 and 150, with ring 148 having a distal facing extension with threads 152 facing radially outward and ring 150 having a distal and radially inward facing extension 154 and threads 154 facing radially inward and mated with threads of 152. As one of rings 148 and 150 is rotated opposite to the other of rings 148 and 150, the space between sheath 104, slider 144 and graft 106 is filled so that the proximal ends of slider 104 and graft 106 is maintained in place.

Referring now to Figures 16 and 17, an alternate version of a locking member 158 is shown which maintains the proximal end of a sheath 160 in a stationery position. Sheath 160 differs from sheaths 19 and 104 previously described in that the thicker part 162 at the proximal end thereof extends over vertical cut 138 and a vertical cut 164 is made entirely through the wall of the thicker part 162 of sheath 160. The vertical cuts 138 and 164 are best

seen in Figure 17. Locking member 140 then is placed through both vertical cuts 138 and 164 and thereby secures the proximal end of sheath 160.

Referring now to Figure 18, an alternate version of the apparatus to secure the distal end of graft 106 is shown. In Figure 18, elastic member 134 is replaced by slotting the distal end 165 of graft securing shaft 130 shaping the interior surface of the distal end 165 of graft securing shaft 130 to be slanted outward and the shape of ledge 166 to be slanted inward. With these shapes, when graft securing shaft moves forward, end 165 sliding over ledge 166 act as a wedge against graft 106, thereby securing graft 106.

Referring now to Figures 19 and 20, an alternate version of a securing mechanism 168 is shown. Securing mechanism 168, like securing mechanism 102, functions to laterally move central shaft 108 and graft securing shaft 130. The difference is that with securing mechanism 168, levers 170 and 172 are moved in guide slots 174 and 176, as opposed to rotating shafts 108 and 130 while holding shaft 120 stationary. More specifically, securing mechanism 168 includes an outer casing 178 having a proximal opening around central shaft 108 and a distal opening around graft securing shaft 130. An extension 180 is provided radially outward from central shaft 108 and an extension 182 is provided at the proximal end of graft securing shaft 130. Levers 170 and 172 extend outward from extensions 180 and 182. A spring 184 is placed between extension 180 and the proximal end of casing 178 and a spring 186 is placed between extension 182 and the distal end of casing 178. Springs maintain levers 170 and 172 in the position shown in Figures 19 and 20 such that graft 106 and sheath 104 are in the unsecured position. To secure graft 106 and sheath 104, levers 170 and 172 are moved in slots 174 and 172 to the locked position at locations 188 and 190.

In order to use tool 100 as described with respect to Figures 11-14, or as modified as described with respect to Figures 15-20, it is first loaded. Generally, the loading of tool 100 is similar to the loading of tool 10 described above with respect to Figures 5-8, except as noted below. As noted above, the combination of central shaft 108, stationary shaft 120 and securing shaft 130 correspond to shaft 18 seen in Figures 5-8. First, slider 144 is placed over shaft securing 130 on the proximal side of cut 138 and locking member 140 is inserted through cut 138 around securing shaft 130.

Next, graft 106 is slid over securing shaft 130 and positioned so that the proximal end is close to or against locking member 14 and the distal end is covering either elastic member 134 or the distal end 165 of securing shaft 130, while at the same time being remote from slot 122. Thereafter, graft 106 is secured in place by rotating securing shaft 130 with respect to stationary shaft 120. At this point, graft 106 is fixed with respect to shafts 120 and 130 and sheath 104 may be slid over graft 106 and secured in slot 122 using guide funnel 52, as described above with respect to Figures 2-4. Finally, slot 122 is closed by rotating the proximal facing extension 116 of central shaft 108 with respect to stationary shaft 120. At this point, tool 100 is loaded and ready to be used to place graft 106 in an artery.

In performing the bypass type procedure in a blood vessel, loaded tool 100 is inserted in the blood vessel being treated, to a point distal from locking member 140. Thereafter, locking member 140 is removed and sheath 104 is unlocked by rotating the proximal facing extension 116 of central shaft 108 with respect to stationary shaft 120. Next, sheath 104 is slid over deployment slider 144 so that the thickened portion of deployment slider 144 adjacent to where locking member 140 had been positioned is exposed. At this point, graft 106 is unlocked by rotating securing shaft 130 with respect to stationary shaft 120 in the oppo-

site direction and shafts 108, 120 and 130 are removed while holding the thickened portion of deployment slider 144 against graft 106. At this point, graft 106 remains in the blood vessel being treated and the physician completes the bypass type procedure by suturing the proximal end of graft 106 in place.

While the invention has been described in its preferred forms or embodiments with some degree of particularity, it is understood that this description has been given only by way of example and that numerous changes in the details of construction, fabrication and use, including the combination and arrangement of parts, may be made without departing from the spirit and scope of the invention.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. Apparatus (10, 60, 76 and 100) for the intraluminal insertion and deployment of a medical graft (14, 106) within a blood vessel characterized by shaft means (18 and 108, 120, 130) for slidably receiving said medical graft (14, 106), a sheath (19, 104) mounted over said graft (14, 106), and means (32, 102, 122, 168) for selectively securing said sheath (19, 104) to said shaft means (18 and 108, 120, 130).

2. Apparatus (10, 60, 76 and 100) for the intraluminal insertion and deployment of a medical graft (14, 106) within a blood vessel characterized by a shaft (18 and 108, 120, 130) having a tapered tip (30, 64, 80, 109) at a distal end (12, 110) and a body extending from said tapered tip (30, 64, 80, 109) to a proximal shaft end (28, 112), said medical graft (14, 106) being slideably mounted on said body remote from a distal portion of said shaft (18 and 108, 120, 130) and a sheath (19, 104) having a proximal portion slideably mounted over said medical graft (14, 106), said sheath (19, 104) having a distal end removably engaging said distal portion of said shaft (18 and 108, 120, 130) to form a taper (40) towards said tapered tip (30, 64, 80, 109) of said shaft (18 and 108, 120, 130), said sheath (19, 104) being fixedly maintained over said medical graft (14, 106) and engaging said distal portion of said shaft (18 and 108, 120, 130) during insertion and said shaft (18 and 108, 120, 130) and sheath (19, 104) being removable for deployment of said medical graft (14, 106).

3. The apparatus (10, 60, 76 and 100) of Claim 2 further characterized by said distal portion of said shaft (18 and 108, 120, 130) including a circumferential slot (32, 122) near said tapered tip (30, 64, 80, 109) and said dis-

tal end of said sheath (19, 104) being divided into a plurality of tabs (42) extending into said circumferential slot (32, 122).

4. A kit characterized by the apparatus (10, 60, 76 and 100) of Claim 3 and an assembly tool (52) having a cavity (58) for placement over said tapered tip (30, 64, 80, 109) to direct said tabs (42) into said circumferential slot (32, 122).

5. The apparatus (10, 60, 76 and 100) of Claim 2 further characterized by a deployment slider (21, 144) positioned between said medical graft (14, 106) and said proximal portion of said shaft (18 and 108, 120, 130) for maintaining the position of said medical graft (14, 106) during deployment of said graft (14, 106).

6. The apparatus (10, 60, 76 and 100) of Claim 2, 3 or 5, further characterized by safety means (20, 140) removably attached to said shaft (18 and 108, 120, 130) for preventing motion of said sheath (19, 104) toward said proximal shaft end (28, 112).

7. The apparatus (10, 60, 76 and 100) of Claim 2, 3 or 5 further characterized by said shaft (18 and 108, 120, 130) including an axial aperture (23) extending therethrough from said proximal shaft end (28, 112) to said tapered tip (30, 64, 80, 109).

8. The apparatus (10, 60, 76 and 100) of Claim 2, 3 or 5, further characterized by an electrical heating element (66) at said tapered tip (30, 64, 80, 109) and means (72) for providing electrical current to said heating element (66).

9. The apparatus (10, 60, 76 and 100) of Claim 8, further characterized by a temperature sensing device at said tapered tip (30, 64, 80, 109), providing an output signal indicating a temperature measured at said tapered tip (30, 64, 80, 109) and means for controlling electrical current provided to said heating element in response to said output signal.

10. The apparatus (10, 60, 76 and 100) of Claim 2, 3 or 5, further characterized by said medical graft (14, 106) is a hollow cylinder with having extensions (15) extending from an outer surface thereof.

11. Apparatus (10, 60, 76 and 100) for the intraluminal insertion and deployment of a medical graft (14, 106) within a blood vessel characterized by a shaft (18 and 108, 120, 130) with a tapered distal tip (30, 64, 80, 109), a first, second and third integral and adjacent aligned cylindrical portions extending proximally from said tapered distal tip (30, 64, 80, 109) to a proximal shaft end (28, 112), said medical graft (14, 106) being slidably positioned on said shaft (18 and 108, 120, 130) around said second cylindrical portion, a deployment slider (21, 144) slideably positioned on said shaft (18 and 108, 120, 130) around said third cylindrical portion, a sheath (19, 104) having a proximal portion slideably mountable between said deployment slider (21, 144) and said medical graft (14, 106), and a distal portion of said sheath (19, 104) having a releasable tapered end (40) removably engaging said first cylindrical portion, wherein movement of said sheath (19, 104) proximally towards said proximal shaft end (28, 112) disengages and releases said sheath (19, 104) tapered end (40) and uncovers said medical graf (12, 106), and means (32, 122) for locking said sheath (19, 104) in engagement with said first cylindrical portion.

12. The apparatus (10, 60, 76 and 100) of Claim 11 characterized in that said first cylindrical portion of said shaft (18 and 108, 120, 130) includes a circumferential slot (32, 122) and said distal portion of said sheath (19, 104) is divided into a plurality of tabs (42) extending into said circumferential slot (32, 122).

13. Apparatus (100) for the intraluminal insertion and deployment of a medical graft (106) within a blood vessel characterized by shaft means (108, 120, 130) for slidably receiving said medical graft (106), a sheath (104) mounted over said graft (106), and means (102, 168) for selectively securing said sheath (104) to said shaft means (108, 120, 130) to prevent the sliding of said sheath (104) during insertion of said apparatus (100) and to permit said sheath (104) to be slideably removed during deployment of said medical graft (106).

14. The apparatus (100) of Claim 13 characterized in that a distal portion (110) of shaft means (108, 120, 130) includes a circumferential slot (122) and a distal (40) end of said sheath (104) extends into said circumferential slot (122), said means (102, 168) for selectively securing varies the width of said slot (122).

15. The apparatus (100) of Claim 14 characterized in that the width of said slot (122) is reduced to secure said distal end of said sheath (104) in said slot (122) during insertion and increased to free said sheath (104) during deployment.

16. The apparatus (100) of Claim 15 characterized in that said distal end (40) of said sheath (104) is divided into a plurality of tabs (42) which extend into said slot (122).

17. The apparatus (100) of Claim 14, 15 or 16 characterized in that said shaft means (108, 120, 130) includes at least two concentric shafts (108, 120) having distal ends defining said slot (122), said means (102, 168) for selectively securing axially moving said two concentric shafts (108, 120) relative to one another.

18. The apparatus (100) of Claim 13 characterized in that said means (102, 168) for selectively securing further includes means (102, 168) to secure said graft (106) to said shaft means (108, 120, 130) to prevent the sliding of said graft (106) while said sheath (104) is removed.

19. The apparatus (100) of Claim 18 characterized in that said shaft means (108, 120, 130) is selectively expandable within said graft (106), said means (102, 168) for securing further expanding said shaft means (108, 120, 130) to secure said graft (106) to said shaft means (108, 120, 130) and for contracting said shaft means (108, 120, 130) to permit relative movement between said shaft means (108, 120, 130) and said graft (106).

20. The apparatus (100) of Claim 19 characterized in that said shaft means (108, 120, 130) includes at least two concentric shafts (120, 130), said means (102, 168) for selectively securing axially moving said two concentric shafts (120, 130) relative to one another to expand and contract said shaft means (108, 120, 130).

21. The apparatus (100) of Claim 18, 19 or 20 characterized in that a distal portion of shaft means (108, 120, 130) includes a circumferential slot (122) and a distal end (40) of said sheath (104) extends into said circumferential slot (122), said means (102, 168) for selectively securing includes means (102, 168) to vary the width of said slot (122).

22. The apparatus (100) of Claim 21 characterized in that the width of said slot (122) is reduced to secure said distal end (40) of said sheath (104) in said slot (122) during insertion and increased to free said sheath (104) during deployment.

23. The apparatus (100) of Claim 22 characterized in that said distal end (40) of said sheath (104) is divided into a plurality of tabs (42) which extend into said slot (122).

24. The apparatus (100) of Claim 23 characterized in that said shaft means (108, 120, 130) includes at least two concentric shafts (108, 120) having distal ends defining said slot (122), said means (102, 168) for selectively securing axially moving said two concentric shafts (108, 120) relative to one another.

25. The apparatus (100) of Claim 21 characterized in that said shaft means (108, 120, 130) includes at least two concentric shafts (108, 120) having distal ends defining said slot (122), said means (102, 168) for selectively securing axially moving said two concentric shafts (108, 120) relative to one another.

26. The apparatus (100) of Claim 25 characterized in that said shaft means (108, 120, 130) includes at a third concentric shaft (130), said means (102, 168) for selectively securing axially moving said third concentric shafts (130) and one (120) of said first two concentric shafts relative to one another to expand and contract said shaft means (108, 120, 130).

27. Apparatus (100) for the intraluminal insertion and deployment of a medical graft (106) within a blood vessel characterized by shaft means (108, 120, 130) for slidably receiving said medical graft (106), a sheath (104) mounted over said graft (106), and means (102, 168) for selectively securing said sheath (104) and said graft (106) to said shaft means (108, 120, 130) to prevent the sliding of said sheath (104) during insertion of said apparatus (100) and to permit said sheath (104) to be slideably removed during deployment of said medical graft (106) without causing movement of said graft (106).

28. The apparatus (100) of Claim 27 characterized in that said apparatus (100) further includes a deployment slider (144) positioned between said graft (106) and a proximal end (112) of said shaft means (108, 120, 130), said sheath (104) being slid towards said proximal end (112) and over said deployment slider (144), said deployment slider (144) maintaining the position of said graft (106) as said shaft means (108, 120, 130) is removed from said graft (106) during deployment.

29. The apparatus (100) of Claim 27 or 28 characterized in that said shaft means (108, 120, 130) includes three concentric shaftss (108, 120, 130), said means (102, 168) for securing including means (102, 168) for axially moving the center concentric shaft (120) and one (108) of said remaining shafts relative to one another to secure said sheath (104) and for axially moving the center concentric shaft (120) and the other one (130) of said remaining shafts relative to one another to secure said graft (106).

30. The apparatus (100) of Claim 29 characterized in that the distal portions of said intermediate shaft (120) and said one shaft (108) define a slot (122) having a variable width, a distal end (40) of said sheath (104) extending into said slot (122) and being secured therein when said slot (122) is contracted and being freed for removal from said slot (122) when said slot (122) has an expanded width.

31. The apparatus (100) of claim 30 characterized in that the distal portions of said intermediate shaft (120) and said other shaft (130) vary the diameter of said shaft means (108, 120, 130) as a result of the relative axial movement of said intermediate shaft (120) and said other shaft (130), the expansion of the diameter of said shaft means (108, 120, 130) securing said graft (106) to said shaft means (108, 120, 130) and the subsequent contraction of said shaft means (108, 120, 130) permitting said shaft means (108, 120, 130) to be withdrawn from said graft (106) during deployment.

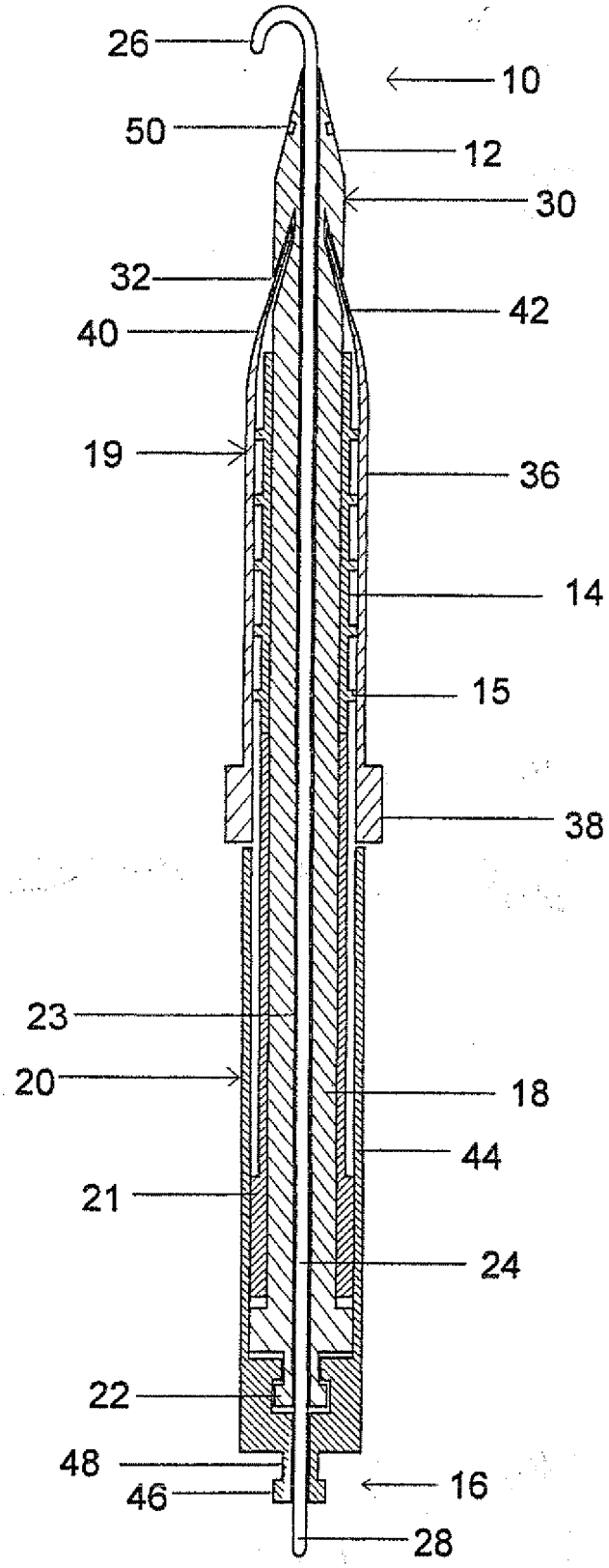


FIGURE 1

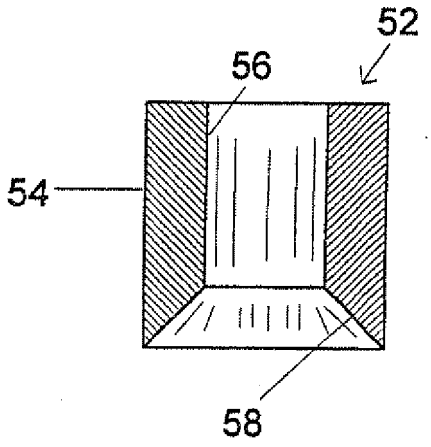


FIGURE 4

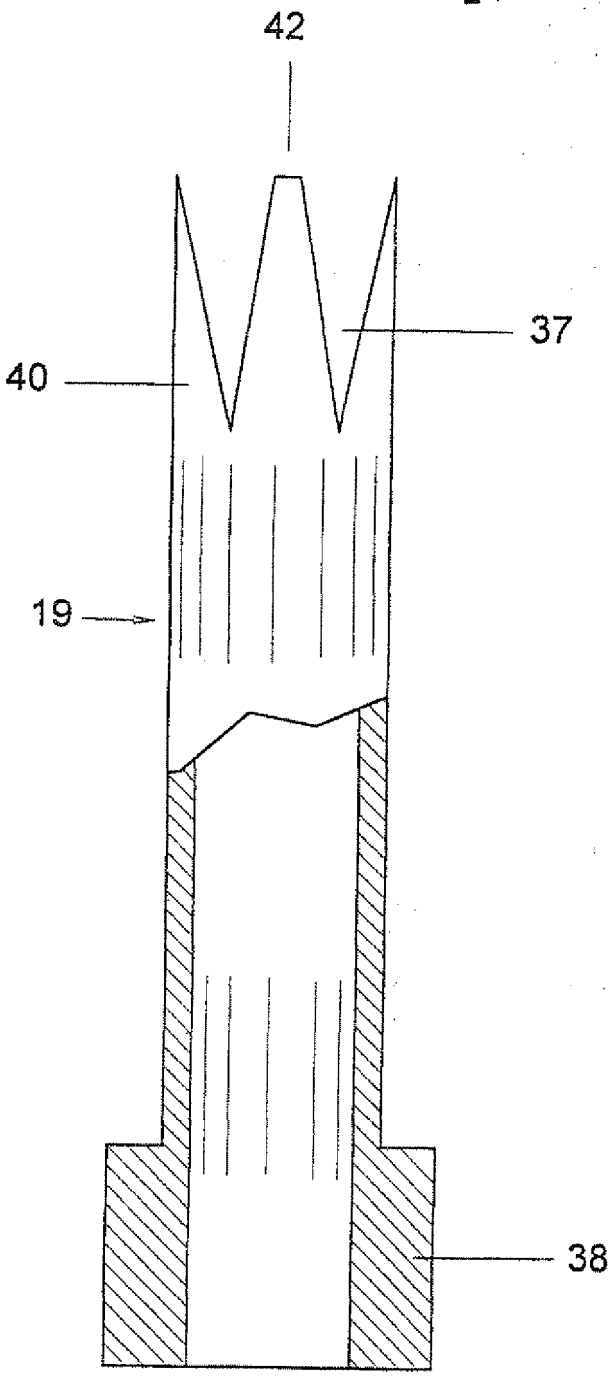


FIGURE 2

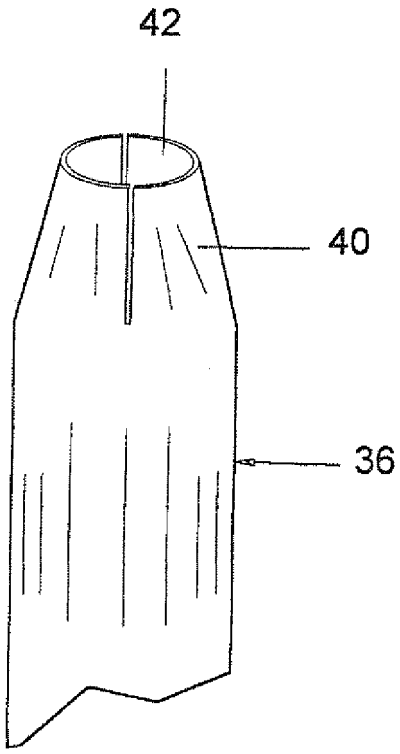


FIGURE 3

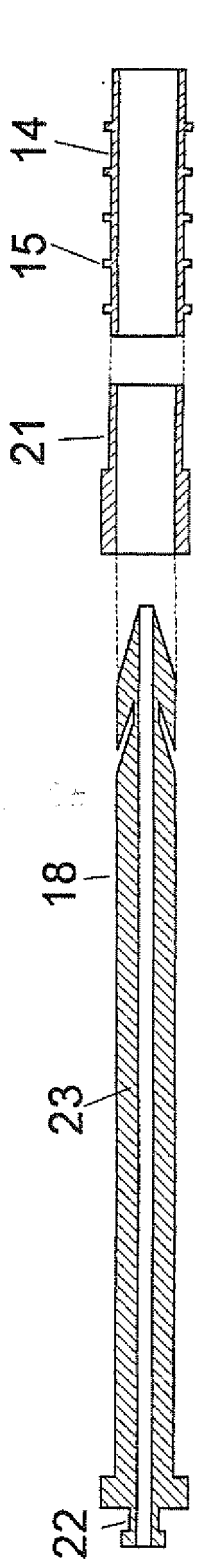


FIGURE 5

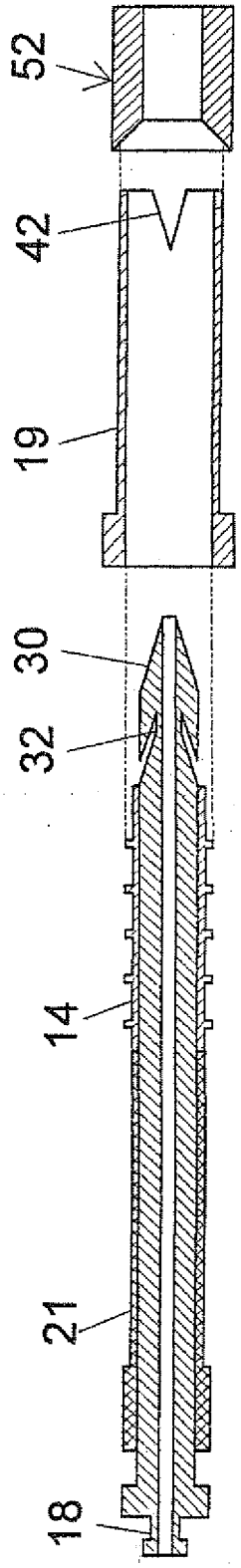


FIGURE 6

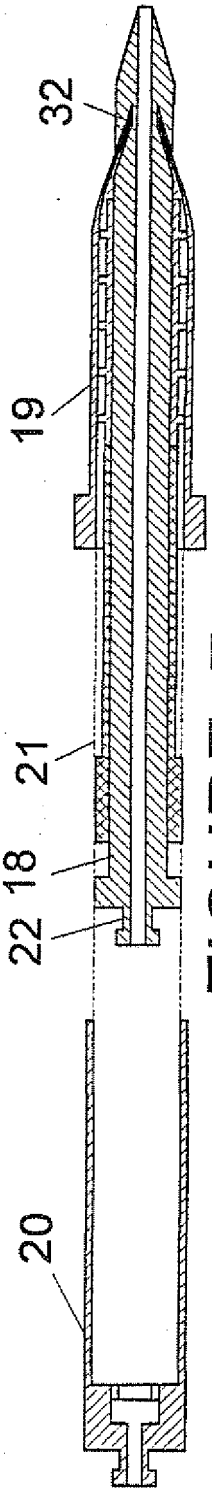


FIGURE 7

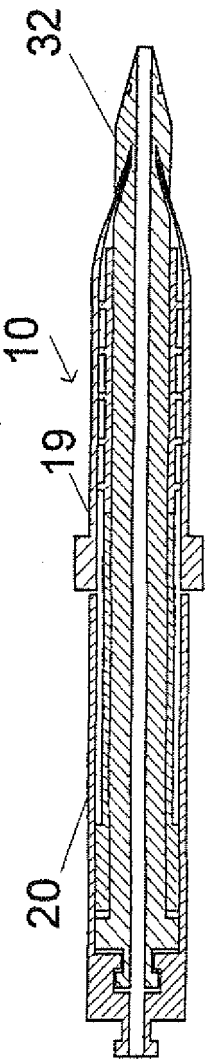


FIGURE 8

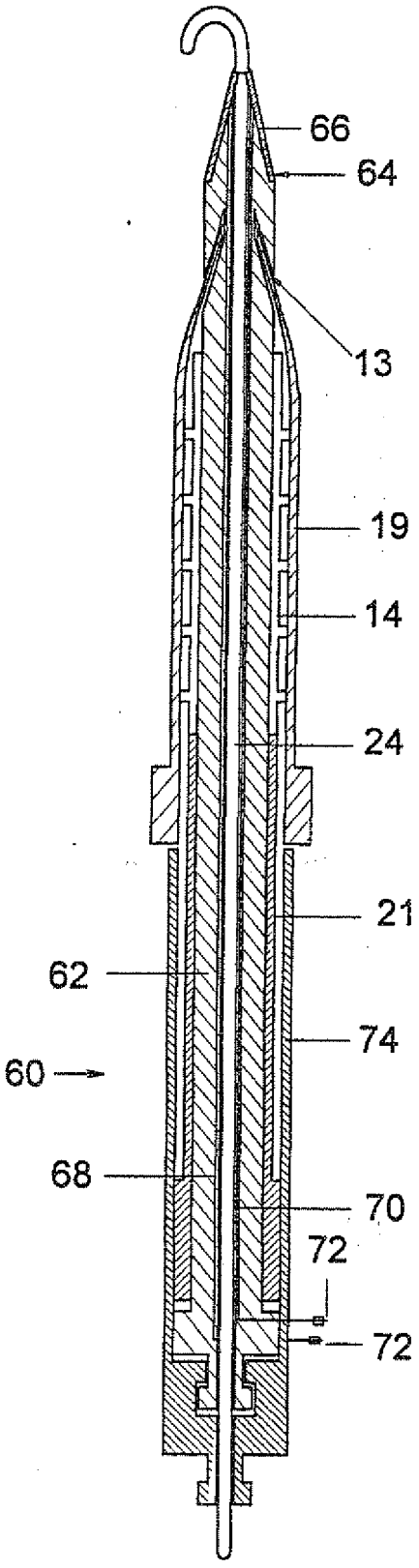


FIGURE 9

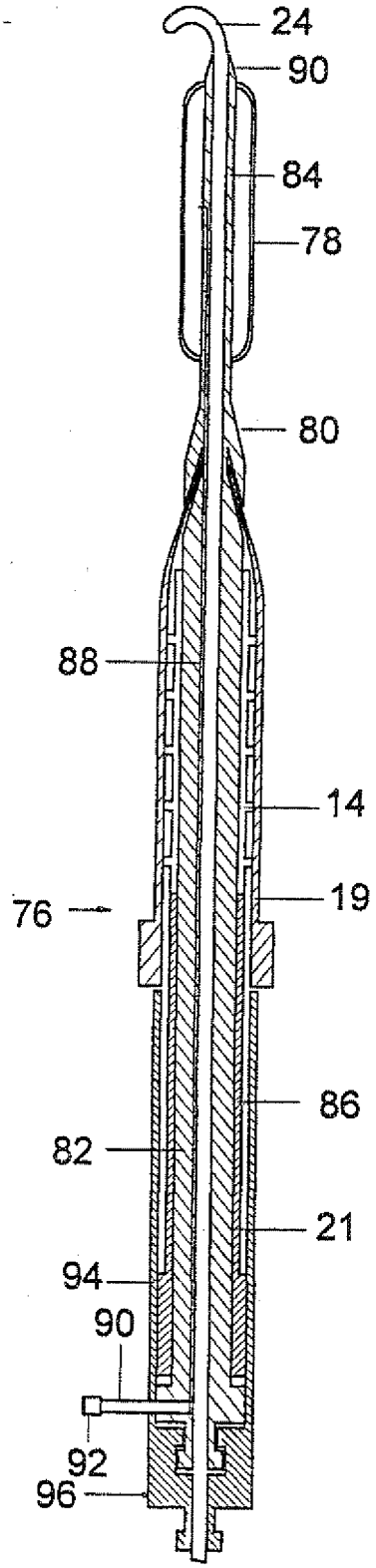


FIGURE 10

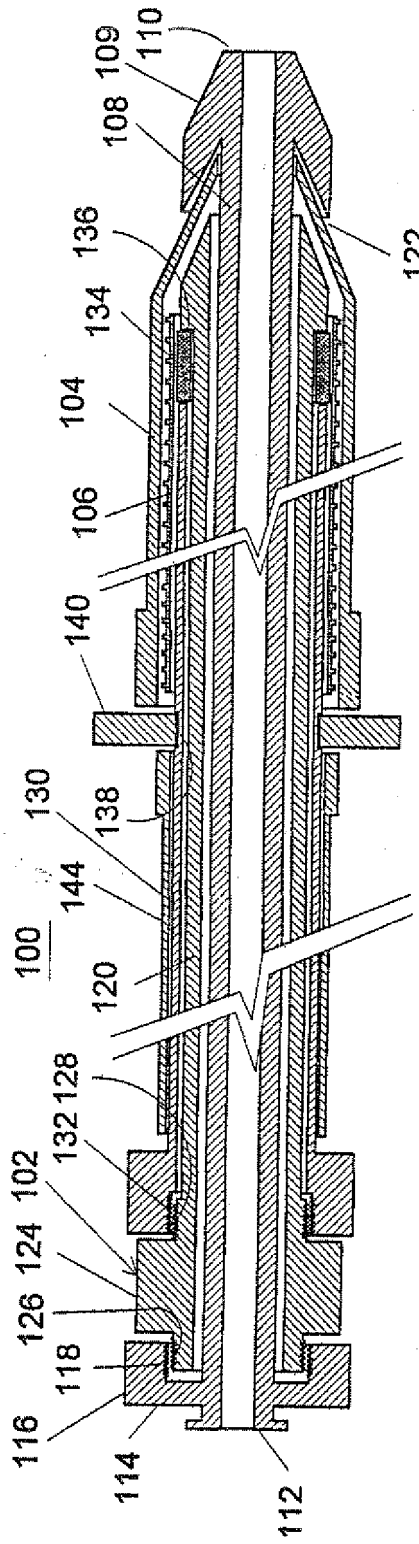


FIGURE 11

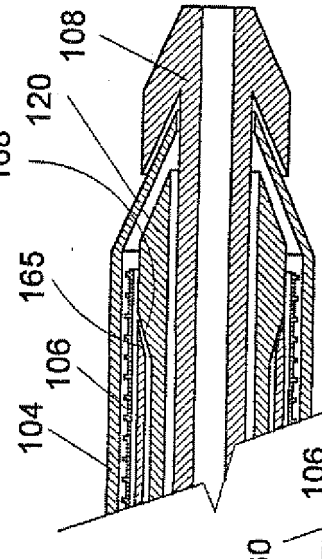


FIGURE 18

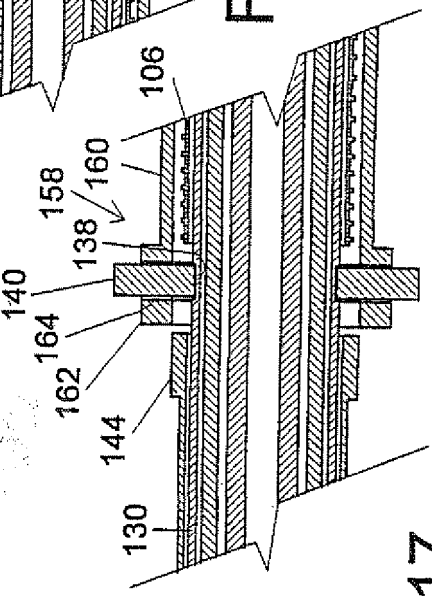


FIGURE 16

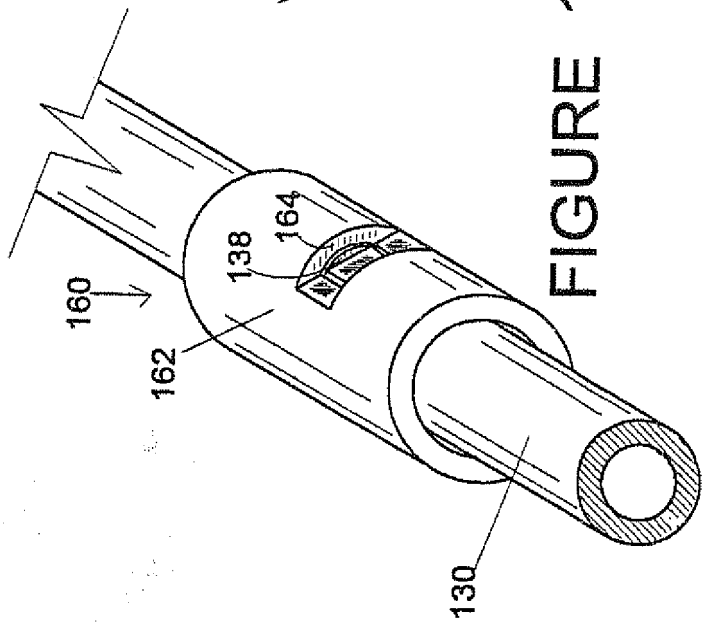


FIGURE 17

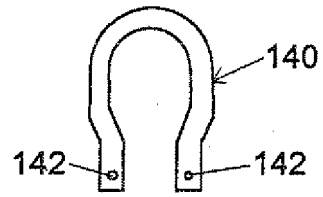


FIGURE 12

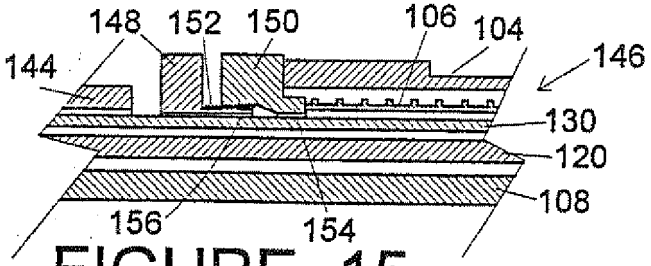


FIGURE 15

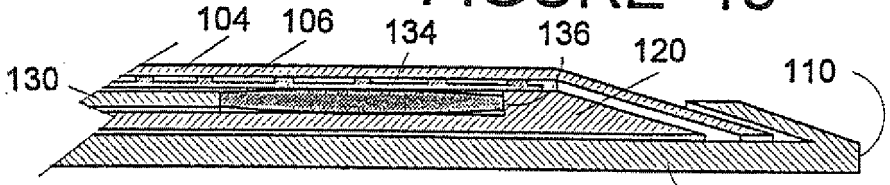


FIGURE 13

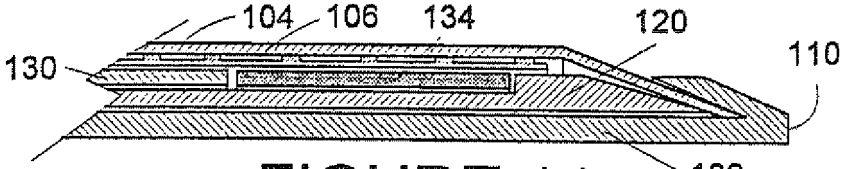


FIGURE 14

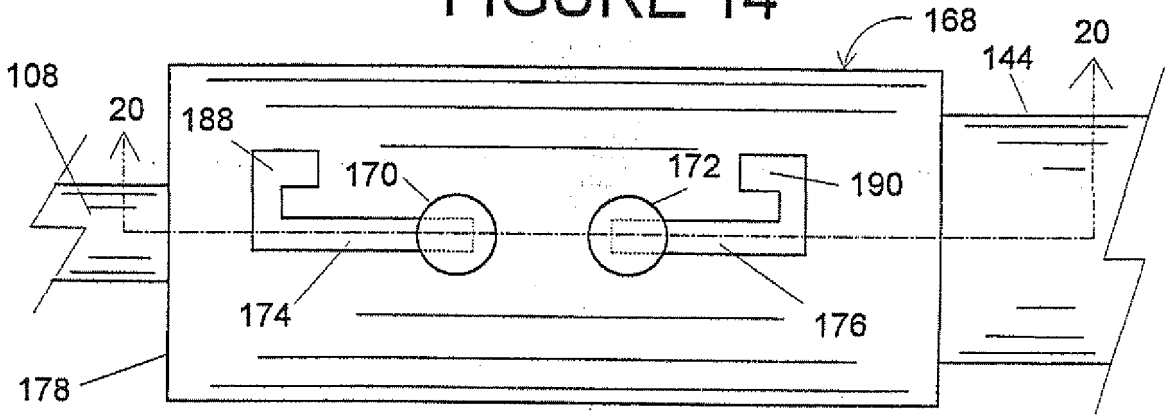


FIGURE 19

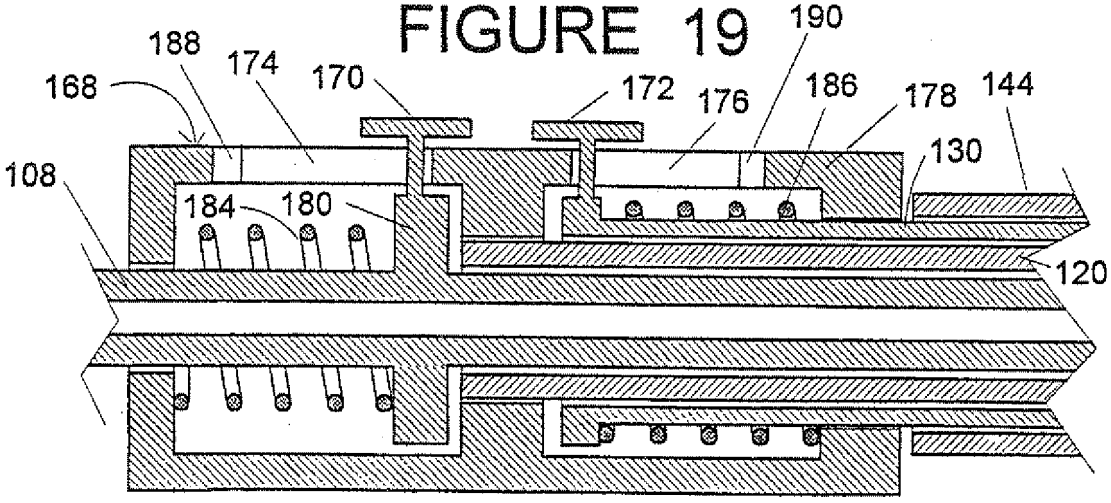


FIGURE 20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/02246

A. CLASSIFICATION OF SUBJECT MATTER
IPC(5) :A61M 29/00
US CL :604/264; 606/31, 108, 194; 623/1, 12
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/164, 165, 171, 263, 264; 606/1, 27-31, 108, 192, 194; 623/1, 12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4,665,918, (GARZA ET AL.), 19 May 1987. See entire document.	1, 13, 27
A	US, A, 4,732,152, (WALLSTEN ET AL.), 22 March 1988.	1-31
A	US, A, 4,739,762, (PALMAZ), 26 April 1988.	1-31
X, E	US, A, 5,290,295, (QUERALS ET AL.), 01 March 1994. See entire document.	1-13, 18, 27, 28

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 09 AUGUST 1994	Date of mailing of the international search report 23 SEP 1994
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer GLENN KEITH DAWSON Telephone No. (703) 308-4304

Form PCT/ISA/210 (second sheet)(July 1992)*